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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,898	07/17/2003	Bradford Evan Gliner	33734-8059US	2827

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,898

Applicant(s)

GLINER ET AL.

Examiner

Carl H. Layno

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-50 is/are allowed.
- 6) ☒ Claim(s) 1,4,5,9,12,14 and 16 is/are rejected.
- 7) ☒ Claim(s) 2,3,6-8,10,11,13,15,17 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority filing based upon U.S. Provisional Application No. 10/432,073, filed December 9, 2002.

Drawings

2. Applicant's formal drawings were received by the Office on July 17, 2003. These drawings have been approved by the Examiner.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. **It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.**

As currently written, the disclosure is objected to because lines 1 and 2 of the Abstract include the phrases "...are disclosed" and "...the invention..." To overcome these objections, the Examiner recommends combining the first and second sentences of the Abstract to read: "A method for treating essential tremor includes directing a patient to perform a muscle action, for example a postural or kinetic muscle action."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 4, 5, 9, 12, 14, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Firlik et al '419-A1.

The Firlik et al '419-A1 patent describes a method for effectuating a change in a neural-function of a patient. Among other methodologies and functions, the reference describes a diagnostic feature in which an "affected limb" is directed to be moved by either a doctor or patient (paragraph [0069], lines 12-19) in order to produce neural signals in a particular part of the brain. See also paragraph [0098]. This location in the brain can be identified using imaging techniques, such as MRI. An identified brain location can then be used for the positioning and insertion of stimulation electrodes **104** (Fig. 1C), and the application of a therapeutic electrical stimulation current **106**. The treatment of Firlik et al is used to treat a variety of motor functions, inherently including finger or hand movements associated with "essential tremor" (paragraph [0064, lines 4-8]).

In regard to claims 4 and 5, applicant's attention is directed to the brain images of Figs. 2-4, which appear to highlight regions of unusual neural activity in the brain **220,230**.

In regard to claim 12, the device of Firlik et al may apply stimulation pulses in the range of 40-200 Hz (paragraph [0092], line 9).

Allowable Subject Matter

6. Claims 2, 3, 6-8, 10, 11, 13, 15, 17, and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 19-50 are allowed.

8. The following is a statement of reasons for the indication of allowable subject matter:

Independent claims 19, 26, 34, and 42 recite similar, yet different, methods for treating essential tremor not found in the prior art. Applicant's claim 19 recites a unique combination of steps including monitoring images of the patient's brain when a patient's muscles are at rest and when being used then comparing the images to identify stimulation sites. Similarly, claim 26 monitors the neural activity in the left and right hemispheres of a patient's brain when muscle actions occur then bases the location of a stimulation site upon this information. Claim 34 performs similar method steps as claim 26 but uses two different muscles to activate the neural activity in two hemispheres of the patient's brain. Claim 42 discloses methods similar to those of claims 19, 26, and 34, but collects neural activity information due to muscle activation while

Art Unit: 3762

the patient is under the influence of drugs. Essential tremor is then treated by applying electrical stimulation to the sites identified by all of these methods. Unable to find these combinations of steps in the prior art, the Examiner deems these claims and their depending claims to be allowable.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Gielen '958-A2 European patent describes a system for optimized brain stimulation for treating neurological disorders, such as Parkinson's disease. Although the patent describes a method for locating ideal stimulation sites within the brain for treating affected limbs, it fails to meet applicant's step of collecting neural activity information, rather feedback information appears to be in the form of patient physical movements and does not appear to be "collected"/stored as data.

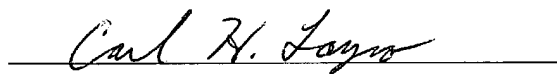
The DiLorenzo '813, John '328, Tcheng et al '457-A1, and Siverstone '044 references are cited for their pertinent tremor treatment methodologies. Unlike applicant's claimed methods, the methods of treatment described in these references do not involve the step of "directing a patient to perform a muscle action". Instead, the methods of these references simply deliver electrical stimulation therapy to brain sites predetermined by the passive monitoring of previous tremors.

Art Unit: 3762

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed communications should be sent to the Office's new Official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.



CARL LAYNO
PRIMARY EXAMINER

CHL
4/29/04